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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,955	03/31/2006	Bernd Rehm	3652-50	3076

23117 7590 01/18/2007  
NIXON & VANDERHYE, PC  
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ARLINGTON, VA 22203

EXAMINER
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MEAH, MOHAMMAD Y

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/525,955

Applicant(s)

REHM, BERND

Examiner

Mohammad Meah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 30-99 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 30-99 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The claims 30-99 are pending in the instant office action.

The previous restriction requirement is withdrawn because of restriction was done improperly by not restricting the claims based on types of proteins or genes encoding the said proteins used. The corrected restriction is submitted as follows:

#### ***Restriction***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Inventions in claims 30-42 and 59-99 comprise processes of production of polymer particles using microorganisms or transformed cells expressed with three set of genes encoding (1) variety of polymer particle synthesizing genes, (2) variety of polymer binding genes and (3) variety of substrate binding genes. Wherein the genes encoding polymer forming proteins are at least **three separate** class genes encoding three separate class of polypeptides: thiolase, reductase or polymer-synthase; polymer binding domain is also **three separate** class of genes: encoding depolymerase,

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polymer regulase or polymer size controlling proteins and finally **three separate class** of substrate binding domains: oligopeptides, enzyme, non-catalytic proteins. These give rise  $3^3 = 27$  separate classes inventions arise from use of different genes encoding different polypeptides.

Similarly claims 43-54 comprise processes of production of polymer particles using same three set of proteins which also give rise  $3^3 = 27$  separate classes inventions.

Based on these various genes or proteins claims are grouped in following groups of inventions:

Groups 1-27, claims 30-42 and 59-99, drawn to a method of producing biodegradable polymer using microorganism induced with genes encoding polymer forming protein, polymer-binding protein and substrate binding protein wherein group 1 comprise method of producing biodegradable polymer using microorganism induced with gene encoding **thiolase** is the polymer forming gene; group 2 method of producing biodegradable polymer using microorganism induced with gene encoding **a reductase** is the polymer forming gene and **polymer depolymerase** gene encoding polymer particle binding domain polypeptide and an **oligopeptide** gene encoding a biologically active substrate binding domain and so on.

Groups 28-54, claims 43-54, drawn to process of production of biodegradable polymer particles using one or more enzymes wherein group 28 comprise

method of producing biodegradable polymer using proteins comprising **thiolase** is the polymer forming enzyme and **polymer depolymerase** as polymer particle binding domain polypeptide and an **oligopeptide as** biologically active substrate binding domain and so on.

Groups 55-81, claims 55-57, drawn to polymer particles or pharmaceutical preparation comprising said polymer particle, wherein group 55 drawn to polymer particles or pharmaceutical preparation made by the process of groups 1 or 28 and so on..

Groups 82-108, claim 58, drawn to method of treating or preventing a disease of central nervous system by administering polymer particles wherein group 82 comprise polymer particle of group 55 and so on.

3. The inventions listed as Groups 1-108 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups 1-27 do not share same technical feature because each group of groups 1-27 comprise process using microorganism expressed with distinct polymer forming genes ( thiolase, reductase or polymer synthase), polymer binding domain ( depolymerase, polymer regulase, etc) and substrate binding domain ( oligopeptide, enzyme or abzyme, etc) having their special technical features.

Groups 28-54 do not share same technical feature because each group of groups 28-54 comprise processes using distinct polymer forming protein ( thiolase, reductase or polymer synthase), polymer binding domain ( depolymerase, polymer regulase, etc) and substrate binding domain ( oligopeptide, enzyme or abzyme, etc) having their special technical features.

Groups 1-27, groups 28-54 and groups 82-108 do not share same technical feature because they involve different method steps using different substances microorganisms ) groups 1-27) and enzymes ( groups 28-54) having different technical features. Technical features of groups 82-108 are treating diseases which are different from the processes of making polymer particles in groups 1-27 and 28-54.

Although groups 55-81 material are made by groups 1-27 or groups 28-54 processes or used in groups 82-108 metho steps they do not share same technical feature because this product can be made by other processes having difirent technical features such as chemical synthesis.

Furthermore, the only technical feature linking group 1-108 appears to be that they all relate to biodegradable polymer. The biodegradable polymer does not constitute a "special technical feature" as defined by PCT Rule 13.2, because it does not claim a feature which defines a contribution over the prior art as a biodegradable polymer is taught by the prior art such as Madison et al. (Microbiol and Mol boil. 1999, pp 21-53).

4. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

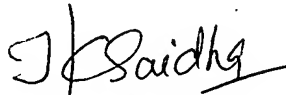
Mohammad Younus Meah, PhD

Examiner, Art Unit 1652

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**TEKCHAND SAIDHA**  
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